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M.P.E.P. Section 716.01, Generally Applicable Criteria

This document contains one section of the Manual of Patent Examining Procedure (the "MPEP"), Seventh Edition (July 1998). This page was last updated in April 2000. All of the sections of the MPEP are found in the [section index](#).



716.01 Generally Applicable Criteria

The following criteria are applicable to all **evidence** traversing rejections submitted by applicants, including affidavits or declarations submitted under [37 CFR 1.132](#):

(A) Timeliness.

Evidence traversing rejections must be timely or seasonably filed to be entered and entitled to consideration. In re Rothermel, 276 F.2d 393, 125 USPQ 328 (CCPA 1960).

Affidavits and declarations submitted under [37 CFR 1.132](#) and other **evidence** traversing rejections are considered timely if submitted:

- (1) prior to a final rejection,
- (2) before appeal in an application not having a final rejection, or
- (3) after final rejection and submitted
 - (i) with a first reply after final rejection for the purpose of overcoming a new ground of rejection or requirement made in the final rejection, or
 - (ii) with a satisfactory showing under [37 CFR 1.116\(b\)](#) or [37 CFR 1.195](#), or
 - (iii) under [37 CFR 1.129\(a\)](#).

(B) Consideration of **evidence**.

Evidence traversing rejections must be considered by the examiner whenever present. All entered affidavits, declarations, and other **evidence** traversing rejections are acknowledged and commented upon by the examiner in the next succeeding action. The extent of the commentary depends on the action taken by the examiner. Where an examiner holds that the **evidence** is sufficient to overcome the prima facie case, the comments should be consistent with the guidelines for statements of reasons for allowance. See MPEP Section 1302.14. Where the **evidence** is insufficient to overcome the rejection, the examiner must specifically explain why the **evidence** is insufficient. General statements such as "the **declaration** lacks technical validity" or "the **evidence** is not commensurate with the scope of the claims" without an explanation supporting such findings are insufficient.

716.01(a)

Objective **Evidence** of Nonobviousness

OBJECTIVE EVIDENCE MUST BE CONSIDERED WHENEVER PRESENT

Affidavits or declarations containing **evidence** of criticality or unexpected results, commercial success, long-felt but unsolved needs, failure of others, skepticism of experts, etc., must be considered by the examiner in determining the issue of obviousness of claims for patentability under 35 U.S.C. 103. The Court of Appeals for the Federal Circuit stated in *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538, 218 USPQ 871, 879 (Fed. Cir. 1983) that "**evidence** rising out of the so-called 'secondary considerations' must always when present be considered en route to a determination of obviousness." Such **evidence** might give light to circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or unobviousness, such **evidence** may have relevancy. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966); *In re Palmer*, 451 F.2d 1100, 172 USPQ 126 (CCPA 1971); *In re Fielder*, 471 F.2d 640, 176 USPQ 300 (CCPA 1973). The *Graham v. John Deere* pronouncements on the relevance of commercial success, etc. to a determination of obviousness were not negated in *Sakraida v. Ag Pro*, 425 U.S. 273, 189 USPQ 449 (1979) or *Anderson's-Black Rock Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969), where reliance was placed upon *A&P Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 87 USPQ 303 (1950). See *Dann v. Johnston*, 425 U.S. 219, 226 n.4, 189 USPQ 257, 261 n. 4 (1976).

Examiners must consider comparative data in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims. In *re Margolis*, 785 F.2d 1029, 228 USPQ 940 (Fed. Cir. 1986). The lack of objective **evidence** of nonobviousness does not weigh in favor of obviousness. *Miles Labs. Inc. v. Shandon Inc.*, 997 F.2d 870, 878, 27 USPQ2d 1123, 1129 (Fed. Cir. 1993), cert. denied, 127 L. Ed. 232 (1994). However, where a prima facie case of obviousness is established, the failure to provide rebuttal **evidence** is dispositive.

716.01(b)

Nexus Requirement and **Evidence** of Nonobviousness

TO BE OF PROBATIVE VALUE, ANY SECONDARY EVIDENCE MUST BE RELATED TO THE CLAIMED INVENTION (NEXUS REQUIRED)

The weight attached to **evidence** of secondary considerations by the examiner will depend upon its relevance to the issue of obviousness and the amount and nature of the **evidence**. Note the great reliance apparently placed on this type of **evidence** by the Supreme Court in upholding the patent in *United States v. Adams*, 383 U.S. 39, 148 USPQ 479 (1966).

To be given substantial weight in the determination of obviousness or nonobviousness, **evidence** of secondary considerations must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the **evidence** of secondary considerations. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 305 n.42, 227 USPQ 657, 673-674 n. 42 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986). The term "nexus" designates a factually and legally sufficient connection between the objective **evidence** of nonobviousness and the claimed invention so that the **evidence** is of probative value in the determination of nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir.), cert. denied, 488 U.S. 956 (1988).

716.01(c)

Probative Value of Objective Evidence

TO BE OF PROBATIVE VALUE, ANY OBJECTIVE EVIDENCE SHOULD BE SUPPORTED BY ACTUAL PROOF

Objective **evidence** which must be factually supported by an appropriate affidavit or **declaration** to be of probative value includes **evidence** of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by **factual evidence**." "[A] ppellants have not presented any experimental data showing that prior heat-shrinkable articles split. Due to the absence of tests comparing appellant's heat shrinkable articles with those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument."). See also *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); *Ex parte George*, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991).

ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE

The arguments of counsel cannot take the place of **evidence** in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not **evidence** and which must be supported by an appropriate affidavit or **declaration** include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

See MPEP Section 2145 generally for case law pertinent to the consideration of applicant's rebuttal arguments.

OPINION EVIDENCE

Although **factual evidence** is preferable to opinion testimony, such testimony is entitled to consideration and some weight so long as the opinion is not on the ultimate legal conclusion at issue. While an opinion as to a legal conclusion is not entitled to any weight, the underlying basis for the opinion may be persuasive. *In re Chilowsky*, 306 F.2d 908, 134 USPQ 515 (CCPA 1962) (expert opinion that an application meets the requirements of 35 U.S.C. 112 is not entitled to any weight; however, facts supporting a basis for deciding that the specification complies with 35 U.S.C. 112 are entitled to some weight); *In re Lindell*, 385 F.2d 453, 155 USPQ 521 (CCPA 1967) (Although an affiant's or declarant's opinion on the ultimate legal issue is not **evidence** in the case, "some weight ought to be given to a persuasively supported statement of one skilled in

the art on what was not obvious to him." 385 F.2d at 456, 155 USPQ at 524 (emphasis in original)).

In assessing the probative value of an expert opinion, the examiner must consider the nature of the matter sought to be established, the strength of any opposing **evidence**, the interest of the expert in the outcome of the case, and the presence or absence of **factual** support for the expert's opinion. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985), cert. denied, 475 U.S. 1017 (1986). See also *In re Oelrich*, 579 F.2d 86, 198 USPQ 210 (CCPA 1978) (factually based expert opinions on the level of ordinary skill in the art were sufficient to rebut the prima facie case of obviousness); *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (statement in publication dismissing the "preliminary identification of a human b-NGF-like molecule" in the prior art, even if considered to be an expert opinion, was inadequate to overcome the rejection based on that prior art because there was **no factual evidence** supporting the statement); *In re Carroll*, 601 F.2d 1184, 202 USPQ 571 (CCPA 1979) (expert opinion on what the prior art taught, supported by documentary **evidence** and formulated prior to the making of the claimed invention, received considerable deference); *In re Beattie*, 974 F.2d 1309, 24 USPQ2d 1040 (Fed. Cir. 1992) (declarations of seven persons skilled in the art offering opinion **evidence** praising the merits of the claimed invention were found to have little value because of a lack of **factual** support); *Ex parte George*, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991) (conclusory statements that results were "unexpected," unsupported by objective **factual evidence**, were considered but were not found to be of substantial evidentiary value).

Although an affidavit or **declaration** which states only conclusions may have some probative value, such an affidavit or **declaration** may have little weight when considered in light of all the **evidence** of record in the application. *In re Brandstadter*, 484 F.2d 1395, 179 USPQ 286 (CCPA 1973).

An affidavit of an applicant as to the advantages of his claimed invention, while less persuasive than that of a disinterested person, cannot be disregarded for this reason alone. *Ex parte Keyes*, 214 USPQ 579 (Bd. App. 1982); *In re McKenna*, 203 F.2d 717, 97 USPQ 348 (CCPA 1953).

716.01(d)

Weighing Objective **Evidence**

IN MAKING A FINAL DETERMINATION OF PATENTABILITY, **EVIDENCE** SUPPORTING PATENTABILITY MUST BE WEIGHED AGAINST **EVIDENCE** SUPPORTING PRIMA FACIE CASE

When an applicant submits **evidence** traversing a rejection, the examiner must reconsider the patentability of the claimed invention. The ultimate determination of patentability must be based on consideration of the entire record, by a preponderance of **evidence**, with due consideration to the persuasiveness of any arguments and any secondary **evidence**. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). The submission of objective **evidence** of patentability does not mandate a conclusion of patentability in and of itself. *In re Chupp*, 816 F.2d 643, 2 USPQ2d 1437 (Fed. Cir. 1987). Facts established by rebuttal **evidence** must be evaluated along with the facts on which the conclusion of a prima facie case was reached, not against the conclusion itself. *In re Eli Lilly*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990). In other words, each piece of rebuttal **evidence** should not be evaluated for its ability to knockdown the prima facie case. All of the competent rebuttal **evidence** taken as a whole should be weighed against the **evidence** supporting the prima facie case. *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984). Although the record may establish **evidence** of secondary considerations which are indicia of nonobviousness, the record may also establish such a strong case of obviousness that

the objective **evidence** of nonobviousness is not sufficient to outweigh the **evidence** of obviousness. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 769, 9 USPQ2d 1417, 1427 (Fed. Cir. 1988), cert. denied, 493 U.S. 814 (1989); *Richardson-Vicks, Inc., v. The Upjohn Co.*, 122 F.3d 1476, 1484, 44 USPQ2d 1181, 1187 (Fed. Cir. 1997) (showing of unexpected results and commercial success of claimed ibuprofen and psuedoephedrine combination in single tablet form, while supported by substantial **evidence**, held not to overcome strong prima facie case of obviousness). See *In re Piasecki*, 745 F.2d 1468, 223 USPQ 785 (Fed. Cir. 1984) for a detailed discussion of the proper roles of the examiner's prima facie case and applicant's rebuttal **evidence** in the final determination of obviousness.

If, after evaluating the **evidence**, the examiner is still not convinced that the claimed invention is patentable, the next Office action should include a statement to that effect and identify the reason (s) (e.g., **evidence** of commercial success not convincing, the commercial success not related to the technology, etc.). See *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir.), cert. denied, 488 U.S. 956 (1988). See also MPEP Section 716.01. See MPEP Section 2144.08, paragraph II.B., for guidance in determining whether rebuttal **evidence** is sufficient to overcome a prima facie case of obviousness.

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